NOV 1 6 2001

K011122

510(k) Summary

1. Submitter Name, Address, and Date of Submission.

Mrs. Julie A. Beaumont
Group Regulatory Affairs Technician
Willy Rüsch AG Group
Tall Pines Park
Jaffrey, New Hampshire 03452

Telephone: (603) 532-7706
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Contact: Same as above

2. Name of the Device, Common, Proprietary (if Known), and Classification.

Classification Name: Needle, Conduction, Anesthetic W/WO Introducer

Common Name: Spinal Anesthesia Needle

Proprietary Name: Ballpen Spinal Needle

3. Identification of the legally marketed device to which the submitter claims equivalence.

The Ballpen Spinal Needle is substantially equivalent to the Pajunk Standard Sprotte needle, K923003 and Spinal Anesthesia Needles and Introducer Cannula, K983858.

4. Description of the Device.

The Ballpen Spinal Needle with/without Introducer consists of a hubbed stainless Stylet, (optional) Bush and protector and (optional) introducer. The Ballpen Spinal Needle comes in various sizes ranging from 18G thru 29G.

5. Intended Use of the Device.

The Ballpen Spinal Needle is intended for spinal anesthesia and lumbar puncture.

6. Summary of Technological Characteristics.

The following technological characteristics are the same as or equivalent to predicate devices:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2001

Mr. Rick Lykins
Rüsch International
Tall Pines Park
Jaffrey, NH 03452

Re: K011122
Ballpen Spinal Needle with/without Introducer
Regulation Number: 868.5150
Regulation Name: Anesthesia Conduction Needle
Regulatory Class: II (two)
Product Code: 73 BSP
Dated: November 2, 2001
Received: November 7, 2001

Dear Mr. Lykins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 6 2001

510(k) Number (if known): K011122

Device Name: Ballpen Spinal Needle with/without Introducer.

Indications for Use:

The Ballpen Spinal Needle with/without Introducer is intended for spinal anesthesia and lumbar puncture.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR _____ Over-The-Counter Use _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011122